Briana Ndife | briana.ndife@novartis.com

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Design of a Disease-Management App to Measure Home-Reported Outcomes (HROs) in Patients (Pts) With IgA Nephropathy (IgAN) and C3 Glomerulopathy (C3G)

Pietro Canetta,[1] Hiba Anwar,[2] Luke Stephens,[2] Rahul Khairnar,[3] Connie Zhang,[2] Samantha McStocker,[2] Amanda Healey,[2] Jordan Owashi,[2] Helen Trenz,[3] Anne Alfano,[4] Aran Rice,[5] Briana Ndife,[3] Mohanram Narayanan[6]

[1]Columbia University, New York, NY, USA; [2]Folia Health, Boston, MA, USA; [3]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; [4]Bondville, VT, USA; [5]Boulder, CO, USA; [6]Baylor Scott & White Medical Center, Temple, TX, USA

KEY SUMMARY POINTS

- The condition-specific platforms, with the design informed by patient and clinician insights, enable tracking of tailored HROs for patients with IgAN and C3G
- As new therapies for IgAN and C3G become available, these insights will provide a timely and valuable understanding of real-world, day-to-day experiences and treatment outcomes in these patients
- By enabling participants to self-select and define what is most relevant to them, rather than relying solely on prespecified patient-reported outcomes, HROs provide a comprehensive and nuanced understanding of the lived experiences of patients with IgAN and C3G
- Thus, in the IgAN Bridge and C3G Connect studies, participants will be able to engage with their own study observations actively, gaining deeper insights into their symptom burden, treatment effects, and acute health events

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INTRODUCTION

- IgAN and C3G are rare, chronic glomerulopathies associated with a high risk of progression to kidney failure[1–3]
- These conditions are characterized by glomerular deposition of either galactose-deficient IgA1-containing immune complexes (in IgAN) or C3 (in C3G), leading to kidney inflammation and injury[1,4]
- There is little published evidence on the humanistic burden of IgAN and C3G; patients who have the same diagnosis may experience different symptoms or prioritize distinct aspects of their condition; therefore, a means of capturing the full spectrum of disease burden is needed
- Patient care could be improved by integrating disease management resources and research participation by allowing patients to track HROs (structured, quantitative observations) that are most relevant to their own disease experience
- Here, we describe the design of two condition-specific platforms for IgAN and C3G within the Folia Health app. These platforms are intended to create a new real-world data source that aims to:
  - Assess the humanistic burden of IgAN and C3G through HROs that capture symptom variability, treatment use, and impact on HRQoL
  - Examine IgAN and C3G HROs based on primary treatment usage

METHODS

- In collaboration with patients with IgAN or C3G and using best practices from Folia Health's previous HRO data collection research studies, study teams designed two condition-specific platforms for IgAN and C3G in the Folia Health App.
- Initial semi-structured interviews were conducted with 3 patients with IgAN, 3 patients with C3G, and 2 clinicians who manage these conditions
- These patient and clinician interviews were used to guide the development of IgAN- and C3G-specific platforms and in-app features including:
  - Tracking of key symptoms, as well as symptom impact on HRQoL
  - Tracking of treatments and measurements, including reasons for switching treatments or treatment discontinuation
  - Capturing key data for use in a dual-purpose tool for patient care management
- These research platforms will be used in app-based, prospective observational research

RESULTS

- The following in-app study features are based on patient and clinician input

IgAN and C3G-Specific Profile Setup

- More than 20 common symptoms and 50 treatments were identified by patients and clinicians for longitudinal tracking (**Figure 1**)
- Observations outside of predefined selections can be recorded
- Participants can create individual treatment schedules, including setting treatment reminders

Detailed Treatment Tracking and Tagging

- Participants can record how treatments impacted their day, including their ability to work or enjoy social activities (**Figure 2**)
- Reasons for skipping treatment (side effects, insurance, etc) can also be noted

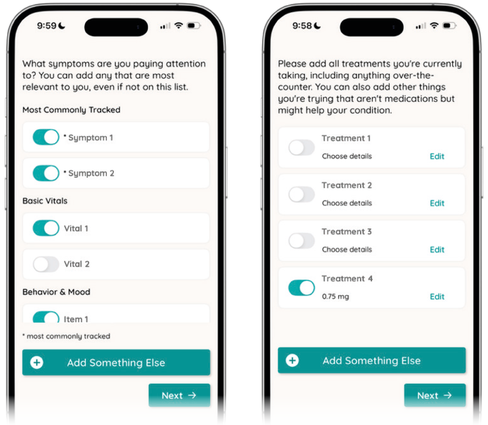
Real-Time IgAN and C3G Flare Tracking

- Flare events can be tracked either outright by the participant or suggested by the application when a key symptom is tracked above baseline (**Figure 3**)
- Flare events can be visualized over time as a summary report with details of severity and instance
- Flares can be correlated to specific triggers of other observations, such as illness, stress, and weather changes
- Treatments (and satisfaction with such treatments) to manage flare events at home will be recorded

Research and Care Management

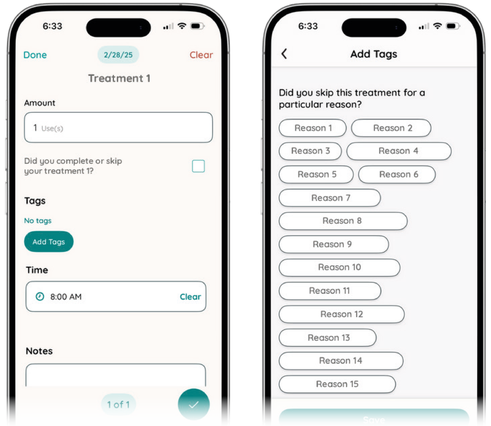
- Data tracked by IgAN and C3G study participants will be automatically summarized into trend reports (**Figure 4**)
- Participants can use their tracked data and subsequent reports during medical appointments to directly inform their care

Figure 1. App Screens of IgAN- and C3G-Specific Symptoms and Treatment Setup



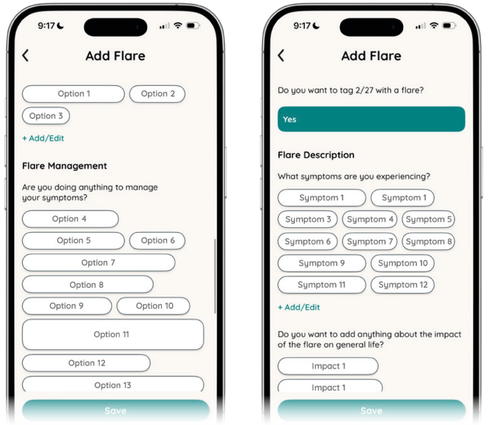
Full list of IgAN symptoms: abdominal pain, anxiety, back pain, blood in urine, blood pressure, bone pain, brain fog, changes in urine, cold sensitivity, daily potassium intake, daily sodium intake, depression, difficult sleeping, fatigue, heat sensitivity, irritability, joint pain, muscle cramping, muscle weakness, shortness of breath, swelling, vision loss, vision distortion, weight. Full list of C3G symptoms: abdominal pain, anxiety, back pain, blood in urine, blood pressure, bone pain, bowel movement, brain fog, cold sensitivity, depression, difficulty sleeping, fatigue, foamy or bubbly urine, frequency of urination, heat sensitivity, irritability, joint pain, muscle cramping, muscle weakness, protein in urine, shortness of breath, swelling, vision loss, vision problems, weight, water intake.
C3G, complement 3 glomerulopathy; IgAN, immunoglobulin A nephropathy.

Figure 2. App Screens of Treatment Tracking and Tagging



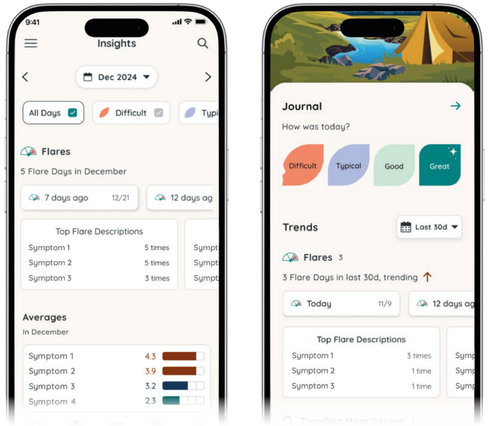
Full list of reasons for skipping treatment: conflicts with another medication, couldn't keep it down, didn't have time, experiencing side effects, forgot today, insurance/payment issues, on vacation, other logistical issues, need to refill or pick up, not feeling well, not sure it's working, taking a break from it, treatment recipient refused, used alternative treatment, wasn't needed, worried about side effects.

Figure 3. App Screens of Flare Tracking and Tagging



Full list of responses for IgAN and C3G flare description symptoms: abdominal pain, back pain, brain fog, cough, dark colored urine, diarrhea, fatigue, fever, flank pain, foamy or bubbly urine, headache, hypertension, sore throat, swelling (edema). Full list of responses for IgAN and C3G flare description impact on quality of life: canceled plans, can't do general activities, can't stop thinking about it, doing okay, experiencing anxiety, experiencing depression, feeling frustrated, felt isolated, felt self-conscious, loss of productivity, missed school, missed work, pushing through it, trouble falling asleep, trouble staying asleep. Full list of responses for IgAN and C3G flare triggers: diet, exercise, illness, nothing specific, not sure, over extended myself, respiratory infection, side-effect from a medication, stress, treatment/medication change, weather change. Full list of responses for IgAN and C3G symptom management: avoiding a suspected trigger, avoiding crowds or social gatherings, contacted doctor from home, didn't need anything, didn't do anything yet, lifestyle modification, medications/supplements at home, not doing anything, other, sleep/rest, went to the doctor, went to the ER, will go to the doctor later if symptoms don't improve. Full list of responses for IgAN and C3G management satisfaction: very well, somewhat, not working at all, N/A.
C3G, complement 3 glomerulopathy; d, day; ER, emergency room; IgAN, immunoglobulin A nephropathy; N/A, not doing anything.

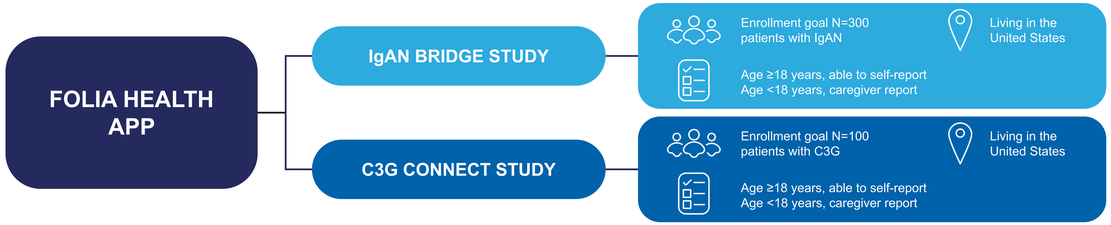
Figure 4. App Screens of Trend Summaries



NEXT STEPS

- The two condition-specific platforms designed for IgAN and C3G in the Folia Health app will be used in future prospective observational research studies
- IgAN Bridge and C3G Connect studies have recently begun enrolling participants (**Figure 5**)

Figure 5. Study Design of Observational Research Studies



C3G, complement 3 glomerulopathy; IgAN, immunoglobulin A glomerulopathy.

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Abbreviations

C3G, complement 3 glomerulopathy; d, day; ER, emergency room; HRO, home-reported outcome; HRQoL, health-related quality of life; IgAN, IgA nephropathy; N/A, not doing anything.

Disclosures

PC has provided paid consultations to Otsuka Pharmaceuticals, Takeda Pharmaceuticals, Travere Therapeutics, and Vera Therapeutics; and has participated in clinical trials sponsored by Calliditas Therapeutics, Novartis, and Travere Therapeutics. **HA**, **LS**, **CZ**, **SM**, **AH**, and **JO** are employees of Folia Health. **RK**, **HT**, and **BN** are employees of Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA. **AA** and **AR** have nothing to disclose. **MN** is an employee of Baylor Scott & White Medical Center; and has received research funding from Novartis.

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